

Compliance Briefing

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DSCSA Enforcement Is Here: What You Need to Know

Whether you're a manufacturer, wholesaler, re-packager, 3PL, or dispenser, DSCSA compliance is not a theoretical future anymore. It's operational reality.

For proof, consider these findings from LSPedia's August 2025 DSCSA Industry Survey:

- 20% of companies have been inspected or audited in the last 90 days
- And 31% have been audited or inspected within the last year

Among all governing bodies, state boards are leading the inspection activities at 11.76%, followed by the FDA (9.8%), "other agencies" (7.84%), and the NABP (5.88%).

We get it—compliance can feel like red tape. But in the pharmaceutical supply chain, it's also the backbone of trust, safety, and operational efficiency. The DSCSA is now in full effect, and unless you're covered by a specific, narrow FDA exemption, it's time to get your systems live, your data flowing, and your teams trained.

Let's break it down with some insight and recommendations.

All DSCSA Requirements Are Now in Effect (Unless You're Exempt)

If your business buys or sells prescription drugs in the U.S., you're subject to DSCSA requirements. That includes:

- Manufacturers and re-packagers
- Wholesale distributors and 3PLs
- Dispensers

If you're still relying on old systems or paper-based workflows, you're officially out of synch with the industry and in danger of incurring penalties and audits. The key requirements—serialization, authorized trading partner verification, suspect product handling, and electronic data exchange—are live and enforceable.

Yes, the FDA granted a few time-limited exemptions. Here's where they stand:

- Small business dispensers (≤ 25 pharmacists/techs) are exempt until Nov. 27, 2026
- Non-small dispensers (≥ 26 employees) are exempt until Nov. 27, 2025

If you're not squarely in one of those categories with a current exemption, you are already expected to be 100% compliant.

Serialized, Package-Level Data Exchange Is Mandatory

Since November 27, 2023, all prescription drug transactions must include package-level data. That means:

Inspection Focus

"The highest priority is that you all... need to have verification systems and processes for the identification and management of suspect and illegitimate product."

— Tish Pahl
Principal & Compliance Expert, OFW

1. Every package must carry a product identifier (GTIN + lot + serial + expiry)
2. You must exchange this information using EPCIS format—securely, electronically, and interoperable
3. You must verify the data, and be ready to trace every package in the event of a recall, investigation, or inspection

Put simply: If you don't receive EPCIS data, you can't accept the product. No data? No business.

Verification Systems Are Non-Negotiable

Verification isn't just a buzzword. It's your legal obligation.

If your business can't detect suspect or illegitimate product, or if you can't respond to a verification request, you're out of compliance and exposing yourself to serious risk. The bare minimum today includes:

- Ability to respond to Verification Router Service (VRS) inquiries
- Custom SOPs for managing suspect and illegitimate products
- Documented employee training aligned with your SOPs

Cut-and-paste SOPs from Google are not allowed. Regulators want to see systems that are implemented, tested, and used—not shelved.

Enforcement Is Already Underway

If you think the FDA and state boards are still in education mode, think again. Federal enforcement includes the following:

- FDA is conducting routine and targeted inspections
- Violations are triggering Form 483s, warning letters, and even criminal indictments

FDA Inspection

FDA issued a 483 Warning Letter in June to Sterling Distributors following the agency's inspection at its Coral Springs, Florida, facility in March 2025. Violations were noted under the DSCSA: Sections 582 of the FD&C Act, also Section 503(e). Sterling Distributors, licensed only for OTC drugs, was caught selling counterfeit GLP-1s to pharmacies. This led to FDA action and a multi-state investigation.

Key enforcement triggers include:

- Failure to report cargo theft
- Unused or canned SOPs
- Lack of verification processes
- Product identifiers missing or mismatched

State enforcement:

- State boards are making live verification requests via VRS
- They're inspecting DSCSA SOPs and vendor compliance
- Counterfeit GLP-1 drugs (like Ozempic) have sparked multi-state investigations

Myths & Misconceptions

There's still a lot of confusion out there. Let's set the record straight.

Myth	Reality
DSCSA doesn't apply to me yet.	If you're a trading partner buying/selling Rx drugs, it does.
Enforcement hasn't started.	Inspections, warning letters, and indictments are ongoing.
There's no patient impact.	Counterfeits are already in the supply chain. DSCSA = Patient Safety.

Business Risks Are Real

What's at stake if you fall behind? Failure to comply with DSCSA may result in:

- Breach of contract with trading partners and GPOs
- Loss of payer/PBM reimbursements
- Civil or criminal liability
- Damage to patient trust and public safety

Regulators demand it. Your customers expect compliance, too. If you aren't complying with the law, that could become evidence of negligence in private lawsuits.

What's Next for Pharmacies?

Pharmacies are the last milestone of the DSCSA enforcement. Big changes are coming to them:

- Product returns must go back to the original distributor matching the sold serial number.
- Pharmacies must have systems in place to track who sold them and the corresponding PO number.
- Dispensers lose their exemption in Nov. 2025 or 2026 (SMB), but inspections are already happening. Are your teams trained and knowledgeable to engage with inspectors?
- Test your systems and procedures now—identify any opportunities and work to close prior to November.

One real-world example: if you bought a drug from Distributor A, you can't return it to Distributor B, even if it's the same NDC. You need to have a system in place to meet compliance and avoid costly mistakes.

How LSPedia Can Help You Get DSCSA-Compliant

You don't have to solve DSCSA on your own. Our platform is built for this moment.

- **EPCIS Exchange via OneScan** – Send and receive serialized data with ease
- **Exception Management via OneScan Investigator** – Spot errors before they reach your dock
- **Product Verification Tools** – Respond to requests, confirm identifiers, and protect your brand
- **Full-Service VRS Integration** – Handle verification without the IT headache
- **SOP Templates & Training** – Get audit-ready with documentation and staff prep
- **Managed Services** – Fractional support to help you scale and comply

Whether you're just starting your DSCSA compliance journey, facing resource shortages, sorting out EPCIS exceptions, dealing with shipment quarantines, or optimizing your live environment, we have the experience, solutions, and people to help.

Ready to Future-Proof Your DSCSA Operations?

We've helped 1,500 companies get ready. We can help you, too. Let's put your compliance program into high gear, without slowing down your business.

- Contact us: trace@lspedia.com
- Get more information: [DSCSA Compliance Checklist](#)
- Register for more insights: [Value Beyond Compliance: Supply Chain Visibility & Strategy Webinar Registration](#)

If you're not sure where to begin, start by reaching out. We'll show you how to get it done—fast, affordably, and with zero guesswork.